UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. 7,140 boxes, more or less, of an article of device, each boxes containing an infusion pump, labeled in part: (box) "*** Manufactured by an affiliate of Baxter Healthcare Corporation Deerfield, IL *** Made in Singapore Baxter *** ONE (1) 2L3113 *** SYNDEO PCA Syringe Pump Voltage 6 VDC ***" (pump) "*** SYNDEO PCA Syringe Pump Baxter Healthcare Corporation Medication Delivery Division Deerfield, IL *** Made in Singapore ***" (box) "*** Manufactured by an affiliate of Baxter Healthcare Corporation Deerfield, IL *** Made in Singapore Baxter *** ONE (1) 2M8161 *** Colleague CX Volumetric Infusion Pump Voltage 100-120V/220-240V ***" (pump) "*** Colleague CX Volumetric Infusion Pump Baxter Healthcare Corporation Medication Delivery Division Deerfield, IL *** Made in Singapore ***" (box) "*** Manufactured by an affiliate of Baxter Healthcare Corporation Deerfield, IL *** Made in Singapore Baxter *** ONE (1) 2M8163 *** Colleague 3 CX Volumetric Infusion Pump Voltage 100-120V/220-240V ***"	No. 05-C-5852 Judge Wayne R. Andersen **CONSENT DECREE FOR CONDEMNATION AND PERMANENT INJUNCTION**

(pump))
)
"*** Colleague 3 CX Volumetric Infusion Pump Baxter) Healthcare Corporation Medication Delivery Division) Deerfield, IL *** Made in Singapore ***")
)
and)
)
all other Baxter Colleague infusion pumps, including) 2M8151 and 2M8153, and Baxter Syndeo PCA syringe) infusion pumps on the premises of Cardinal Health, Inc.,) 2111 Waukegan Road, Waukegan, Illinois, and Baxter) Healthcare Corp., 900 Corporate Grove Drive, Buffalo) Grove, Illinois,)
)
and)
)
BAXTER HEALTHCARE CORPORATION, and) ROBERT L. PARKINSON, JR and PETER J.) ARDUINI, individuals,)
)
Defendants.)
)

On October 12, 2005, plaintiff, the United States of America, by and through its attorneys, filed a verified complaint for forfeiture against certain articles that were in the possession of Baxter Healthcare Corporation ("Baxter"), located in Buffalo Grove, Illinois and Cardinal Health Inc. ("Cardinal"), located in Waukegan, Illinois. The complaint alleged, among other things, that the above-captioned articles (the "Seized Articles") are adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 351(c), 351(h), and 352(t)(2). On October 26, 2005, plaintiff filed an amended *in rem* complaint with substantially similar allegations. Pursuant to each Warrant of Seizure and Monition issued by this court, the United States Marshal for this district seized the articles of device at Cardinal's and Baxter's facilities on October 12, 2005, and at Baxter's facility on October 27, 2005. Baxter filed a statement of interest for the Seized

Articles on November 7, 2005, and its Answer on January 11, 2006, denying the allegations in the amended complaint and asserting affirmative defenses.

The amended complaint alleges, among other things, that certain of the Seized Articles are: (1) adulterated within the meaning of the Act, 21 U.S.C. § 351(c), in that their quality falls below that which they purport and are represented to possess; (2) adulterated within the meaning of the Act, 21 U.S.C. § 351(h), in that the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice ("CGMP") and the Quality System regulation ("QS Regulation") as promulgated under 21 C.F.R. Part 820; and (3) misbranded within the meaning of the Act, 21 U.S.C. § 352(t)(2), in that the firm failed or refused to furnish information required by the Act, 21 U.S.C. § 360(i).

Defendants, Baxter, Robert L. Parkinson, Jr. (who assumed his position as Baxter's Chief Executive Officer on April 26, 2004), and Peter J. Arduini (who assumed his position as Corporate Vice President and President of Baxter's Medication Delivery Services on April 18, 2005) (collectively, the "Defendants"), without admitting the allegations in the complaint and amended complaint, and disclaiming any liability in connection therewith, having appeared, waived the filing and service of a second amended complaint seeking injunctive relief, and, without contest and before any testimony having been taken, agreed to the entry of this decree.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This court has subject matter jurisdiction over this action and personal jurisdiction over all parties pursuant to 28 U.S.C. § 1345 and 21 U.S.C. §§ 332 and 334. Venue is proper in this district under 28 U.S.C. §§ 1391(b)-(c) and 1395.

2. The complaint and amended complaint state a claim for relief against the Seized Articles under the Act, 21 U.S.C. §§ 301-397.

3. Defendant Baxter affirms that it is the sole owner of the Seized Articles, and that no other person has an interest in the Seized Articles. Defendant Baxter further affirms that it shall indemnify and hold the United States harmless should any other party or parties hereafter file or seek to file a statement of interest or right to intervene in this action, or seek to defend or obtain any part of the Seized Articles.

SEIZURE PROVISIONS

4. The Seized Articles are hereby condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

5. The United States shall recover from Defendant Baxter all court costs, fees, and storage and other proper expenses, and such further costs for which Defendant Baxter is liable pursuant to 21 U.S.C. § 334(e) with respect to the Seized Articles. Defendant Baxter shall pay these costs within ten (10) calendar days of receiving written notice from FDA of such costs.

6. A. Pursuant to 21 U.S.C. § 334(d)(1), within twenty (20) calendar days of the entry of this decree, Defendant Baxter shall execute and file with the clerk of this court a good and sufficient penal bond in the form of an irrevocable standby letter of credit (the "Penal Bond") in the amount of twenty million dollars ($20,000,000). The Penal Bond shall be obtained from a trust company or commercial institution in good standing, payable to the United States, valid for at least one year from the date said Penal Bond is approved by this court. The Penal Bond shall be in a form acceptable to the clerk of this court and conditioned on Defendants abiding by and performing

all of the terms and conditions of this decree and of such further orders and decrees as may be entered in this proceeding, and may be drawn upon by the presentation of a sight draft.

B. If Defendant Baxter has not completed the process of destroying or attempting to bring the Seized Articles into compliance with the law, as set forth in paragraph 7, prior to the expiration of the original Penal Bond, or any subsequent Penal Bond, it shall be the responsibility of Defendant Baxter to file with the clerk of this court a new Penal Bond, valid for at least an additional one year, no later than sixty (60) calendar days before the expiration of the previous Penal Bond, and to provide written notice of the posting of such new Penal Bond and a copy thereof to both FDA and the United States Attorney assigned to this case. If, sixty (60) calendar days before the expiration of the original Penal Bond, Defendant Baxter has not completed the process of destroying or attempting to bring the Seized Articles into compliance with the law and has not filed a new Penal Bond with the clerk of this court, the existing Penal Bond shall be immediately payable to the United States of America prior to expiration of such Penal Bond.

7. A. Within forty (40) calendar days of the entry of this decree, and after filing the Penal Bond with this court as provided in paragraph 6 of this decree, Defendant Baxter shall give written notice to FDA that Defendant Baxter, at its own expense, is prepared to attempt to bring the Seized Articles into compliance with the law under FDA's supervision. Defendant Baxter, also within forty (40) calendar days of entry of this decree and filing of the Bond, shall submit to FDA a detailed written plan describing its proposal to bring the Seized Articles into compliance with the Act. The plan shall specifically identify which reconditioning measures apply to which Seized Articles. Defendants shall not attempt to bring the Seized Articles into compliance until they have submitted a written plan to FDA and FDA has provided them with written authorization to

commence attempting to bring the articles into compliance. FDA's decision regarding the adequacy of the reconditioning proposal shall be final.

B. FDA shall notify Defendant Baxter in writing within forty-five (45) calendar days of FDA's receipt of Baxter's reconditioning plan whether the reconditioning plan is acceptable in whole or in part. If the reconditioning plan is acceptable with regard to some of the Seized Articles and not others, FDA shall specify those Seized Articles for which the reconditioning plan is acceptable. If FDA notifies Defendant Baxter in writing that some or all of the reconditioning plan is unacceptable, FDA shall state the basis for such determination. Defendant Baxter shall then submit, within twenty (20) calendar days of receipt of FDA's letter, either a revised reconditioning plan for those articles for which the initial plan was unacceptable or a plan to destroy those articles as set forth below. FDA shall respond in writing within thirty (30) calendar days of its receipt of Baxter's revised reconditioning plan to notify Defendants as to whether the revised plan is acceptable. If Defendant Baxter has not submitted a revised reconditioning plan within twenty (20) calendar days of receipt of FDA's letter, or if FDA finds that the revised reconditioning plan is unacceptable, Defendant Baxter shall cause that portion of the Seized Articles for which no revised reconditioning plan was submitted or for which the revised reconditioning plan was deemed unacceptable, to be promptly destroyed at Defendant Baxter's expense and under the supervision of an FDA representative. Destruction pursuant to this paragraph may take the form of a salvaging operation that permits Defendant Baxter to dismantle specified Seized Articles for the purpose of salvaging and preserving specified parts and components of the Seized Articles, provided that Defendant Baxter first submits such salvaging plan to FDA in writing and receives FDA's written authorization to implement the salvaging plan. If FDA finds that Defendant Baxter's revised

reconditioning plan and/or salvaging plan is unacceptable, in whole or in part, Defendants may challenge that decision under the terms set forth in paragraph 26. Defendants may execute any portion of the initial or revised reconditioning or salvaging plan that was found acceptable by FDA in accordance with the applicable provisions in this decree.

C. Defendants shall not dispose of the Seized Articles or any part of them in a manner contrary to the provisions of the Act, or any other federal law, or of the laws of any state or territory (as defined in the Act) in which they are disposed. All Seized Articles that are not successfully reconditioned as provided in this decree shall be destroyed at Defendant Baxter's expense under the supervision of an FDA representative, and Defendant Baxter shall pay to the United States all costs incurred in supervising the destruction of such articles, at rates specified in paragraph 20 of this decree. If requested by FDA, Defendants shall furnish duplicate copies of invoices of sale of any released devices, or other evidence of disposition as FDA may request.

D. Following Defendants' receipt of written authorization to commence attempting to bring the products into compliance with the Act and following the payment of costs pursuant to paragraph 5 and the posting of the Penal Bond by Defendant Baxter as required by paragraph 6 of this decree, the United States Marshal for this district shall, upon receiving written notice from FDA, release those articles that are specified in FDA's notice to Defendants from his custody to the custody of Defendants for the sole purpose of attempting to bring the articles into compliance with the law, pursuant to the reconditioning proposal(s) approved by FDA as set forth in paragraph 7.

E. Defendants shall at all times, until the Seized Articles have been brought into compliance with the law as determined by FDA or destroyed under FDA supervision, retain the

Seized Articles intact for examination or inspection by FDA in a place made known to and approved by FDA, and shall retain the records or other proof necessary to establish the identity of the Seized Articles.

F. Within ninety (90) calendar days of receiving approval and/or rejection of the reconditioning plan and/or salvaging plan pursuant to paragraph 7, Defendants shall either destroy the Seized Articles at Defendant Baxter's sole expense under the supervision of the FDA representative or complete its attempt to bring the Seized Articles into compliance with the law in the manner set forth in the reconditioning plan and/or salvaging plan found acceptable to FDA. Defendant Baxter shall reimburse the United States for the costs of supervising the reconditioning and/or destruction of the Seized Articles within twenty (20) calendar days of receiving an invoice for such costs at the rates listed in paragraph 20. Defendant Baxter shall also bear all costs of destruction and be responsible for ensuring that such destruction is carried out in a manner that complies with the provisions of the Act, other federal law, and the laws of any state or territory (as defined in the Act) in which they are disposed of. Within twenty-five (25) calendar days of receiving Defendants' written notice to FDA of its completion of its attempt to bring the Seized Articles into compliance with the Act and/or destruction of the articles, FDA shall provide Defendant Baxter with an invoice for the costs of supervising such attempt and/or destruction. Defendant Baxter shall pay those costs within twenty (20) calendar days of receiving FDA's invoice. Upon receipt of such payment from Defendant Baxter, FDA will notify the United States Attorney for this district that Defendants have brought the articles into compliance with the law and/or destroyed the articles, and that Defendant Baxter has paid the costs set forth in FDA's invoice.

G. The United States Attorney for this district, upon being advised by FDA that the Seized Articles have been destroyed or brought into compliance with the Act and its implementing regulations, and that the foregoing conditions of this decree have been performed, shall transmit such information to the clerk of this court, whereupon the Penal Bond given in this proceeding by Defendant Baxter shall be canceled and discharged.

8. If Defendants fail to abide by and perform all of the terms and conditions of this decree, or of the Penal Bond, or of such further order or decree as may be entered in this proceeding relating to the Seized Articles, then the Penal Bond posted as provided in paragraph 6 of this decree shall, on motion of the United States in this proceeding, be forfeited in its entirety and judgment entered in favor of plaintiff. In addition, if Defendants breach any term or condition of this decree or such further order or decree as may be entered in this proceeding, then Defendant Baxter shall, at its own expense, immediately return the Seized Articles to the United States Marshal for this district or otherwise dispose of them pursuant to an order of this court. Following return of the articles to the United States, the Marshal shall destroy the Seized Articles and make due return to this court. In the event that destruction of the Seized Articles by the Marshal becomes necessary pursuant to this paragraph, Defendant Baxter shall be responsible for all costs of storage and disposition that are incurred by the United States.

9. Defendants shall at no time, and under no circumstances whatsoever, ship, sell, offer for sale, or otherwise dispose of the Seized Articles, or any part thereof, until: (a) FDA has had free access to the articles in order to take any samples or make any tests or examinations that FDA deems necessary; (b) FDA has notified Defendants in writing that any reconditioning to be conducted in accordance with the reconditioning proposal in paragraph 7 is complete and that the reconditioned

products comply with the Act, its implementing regulations, and this decree; and (c) that FDA has notified the United States Attorney for this district that Defendants have completed their attempt to bring the articles into compliance with the law in accordance with paragraph 7(F).

INJUNCTION PROVISIONS

10. Upon entry of this decree, Defendants, and each and all of Baxter's officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of the contents of this decree by personal service or otherwise, are permanently enjoined, pursuant to 21 U.S.C. § 332(a), subject to the conditions set forth in paragraph 11, from manufacturing, processing, packing, repacking, labeling, distributing, or importing into the United States of America any model or components for its Colleague Volumetric Infusion Pumps (including, but not limited to, models 2M8151, 2M8151R, 2M8161, 2M8161R, 2M8153, 2M8153R, 2M8163, and 2M8163R) ("Colleague Infusion Pumps") and Syndeo Infusion Pumps (including model 2L3113) ("Syndeo Infusion Pumps") (collectively, the "Infusion Pumps"), unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, repack, label, hold, and distribute the Infusion Pumps are established, operated, and administered in compliance with 21 U.S.C. § 351(h) and 21 C.F.R. Part 820;

B. Defendants select and retain, at Defendants' expense, an independent person or persons (the "Expert"), who is qualified by education, training, and experience to conduct inspections at Baxter's facilities that manufacture, process, pack, repack, label, hold, or distribute the Infusion Pumps, or any component thereof (hereafter, the "Infusion Pump Facilities"), and to

review procedures and methods for manufacturing, processing, packing, repacking, labeling, holding, and distributing the Infusion Pumps, to determine whether their methods, facilities, and controls are operated and administered in conformity with 21 U.S.C. § 351(h), 21 C.F.R. Part 820, 21 U.S.C. § 352(t)(2), and this decree. The Expert shall be without personal or financial ties (other than a consulting agreement between the parties) to any officer or employee of Baxter or their immediate families. Defendants shall notify FDA in writing of the identity of the Expert within fifteen (15) calendar days of retaining such Expert;

C. The Expert shall perform a comprehensive inspection of Baxter's Infusion Pump Facilities and their manner of operation and certify in writing to FDA: (1) that he or she has inspected Baxter's Infusion Pump Facilities, processes, and controls; and (2) whether Defendants' operations are, in the Expert's opinion, in conformity with 21 U.S.C. § 351(h), 21 C.F.R. Part 820, 21 U.S.C. § 352(t)(2), and this decree. The Expert's certification report shall include, but not be limited to, the following:

i. Steps taken by Defendants to comply with 21 U.S.C. §§ 351(h) and 352(t)(2);

ii. Steps taken by Defendants to identify the root causes, or if not precisely known, the most probable root causes, for the failures with the Infusion Pumps, and an evaluation whether Defendants have implemented appropriate steps to correct and prevent such failures;

iii. Defendants' procedures for properly and timely reporting adverse events under 21 C.F.R. Part 803;

iv. Steps taken by management with executive responsibility to ensure continuous implementation of an adequate and effective quality system, including specific written procedures governing management review and quality audits;

v. A detailed evaluation of Baxter's current state of compliance with respect to the CGMP and QS Regulation deviations brought to Baxter's attention in writing by FDA and/or FDA investigators since September 16, 1999;

vi. Personnel training to perform product failure, and corrective and preventive action assessment activities; and

vii. Procedures for the Corrective and Preventive Action ("CAPA") system, including, but not limited to: implementing and verifying or validating corrective actions in accordance with 21 C.F.R. §§ 820.75 and 820.1(a)(3); establishing appropriate time frames; conducting and documenting adequate failure investigations; implementing an effective complaint handling system; and properly integrating international databases. The Expert may choose to conduct separate inspections for the methods, processes, and controls for the Colleague and Syndeo Infusion Pumps, and provide separate certification reports for each device.

D. Defendants report to FDA in writing the actions they have taken to ensure that the methods used in, and the facilities and controls used to manufacture, process, pack, repack, label, hold, and distribute the Infusion Pumps are operated and administered and will be continuously operated and administered in conformity with 21 U.S.C. § 351(h), 21 C.F.R. Part 820, 21 U.S.C. § 352(t)(2), and this decree. This report shall include an evaluation of Baxter's current state of compliance with respect to the CGMP and QS Regulation deviations brought to Baxter's attention in writing by FDA and/or FDA investigators since September 16, 1999. Defendants may choose

to provide separate reports to FDA for the Colleague and Syndeo Infusion Pumps for purposes of complying with this paragraph.

E. Within thirty (30) calendar days of receipt of Defendants' report(s) under paragraph 10(D), FDA may, in its discretion and without prior notice, commence an inspection of Baxter's Infusion Pump Facilities to determine whether the requirements of this decree have been met, and whether Baxter's Infusion Pump Facilities are otherwise operated in conformity with 21 U.S.C. § 351(h), 21 C.F.R. Part 820, and 21 U.S.C. § 352(t)(2); and

F. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 10(A)-(E).

G. If Defendants have satisfied the criteria under paragraphs 10(A)-(F) for the resumption of operations with respect to one infusion pump (e.g., Colleague), but not the other (e.g., Syndeo), FDA shall issue the notice under subparagraph (F) to Defendants with respect to the infusion pump satisfying the criteria set forth in this paragraph notwithstanding the fact that the other infusion pump may not have satisfied such criteria.

11. Paragraph 10 of this Decree shall not apply to the following:

A. Any Infusion Pumps and components thereof manufactured, processed, packaged, labeled, or held for sale at Defendants' Infusion Pump facilities located in Singapore ("Singapore Infusion Pump Facilities") are excluded from paragraph 10, insofar and so long as the Singapore Infusion Pump Facilities manufacture and distribute Infusion Pumps and components thereof only to countries other than the United States or that are intended for export from the United States as set forth in paragraph 11(B). However, Defendants' Singapore Infusion Pump Facilities

are enjoined under paragraph 10 from, either directly or indirectly, causing the introduction into interstate commerce of the Infusion Pumps, and/or components thereof.

B. Any Infusion Pumps or components thereof manufactured, processed, packaged, labeled, held for sale, or introduced into interstate commerce solely for export from the United States, provided that the applicable requirements of 21 U.S.C. § 381(e) have been satisfied with respect to any such device or component;

C. Any Infusion Pumps, or components, parts, or accessories thereto, whose manufacture or processing is not intended for human use and is undertaken for the *sole* purpose of developing, testing, verifying, or validating design changes or modifications in accordance with 21 C.F.R. §§ 820.75, 820.1(a)(3), and 820.30(f)-(g), and revised production and process controls, revised manufacturing procedures, or the adequacy of corrective and preventive actions;

D. Any Infusion Pump, component, part, or accessory that is manufactured, processed, packaged, held for sale, or distributed *solely* for the purpose of responding to a written request or written order to provide either routine service maintenance, or to replace components, parts, or accessories for the Infusion Pumps that were already in the possession of customers of Baxter prior to October 12, 2005 or otherwise placed in distribution pursuant to paragraphs 11(E) or 11(F); provided, however, that: (a) Baxter shall send a copy of the notification letter attached hereto as Exhibit A to customers upon providing such routine service maintenance or replacing components, parts, or accessories as set forth herein; (b) any Infusion Pump furnished by Defendants to a customer under this subparagraph shall be the identical device (same model and serial number) that Defendants received from the customer and (c) that Baxter shall maintain a record, and shall allow FDA access to such record upon request, of all such requests or orders and "ship to" records,

which records must include the following: (1) a detailed description of the requested service maintenance; (2) the date of any such request or order; (3) the dates of service; (4) the names, addresses, and telephone numbers of the persons/entities making any such request or order; and (5) a description of Infusion Pump (model and serial number) the components, parts, or accessories used to provide service maintenance. Provided further, however, Baxter shall not be required to provide the notification letter (Exhibit A) to an entity or person with respect to any serviced or repaired pump that has been previously upgraded or modified pursuant to the corrective action plan approved pursuant to paragraph 14 below;

E. Any Infusion Pumps or components thereof manufactured, imported, or distributed pursuant to, and in conformity with a written authorization for medically necessary products as provided by FDA to Baxter pursuant to this subparagraph. Baxter may submit a detailed written request to FDA seeking authorization to distribute Infusion Pumps it believes are medically necessary products. A product is considered to be medically necessary if it is used to treat or prevent a serious disease or medical condition and there is no other available source of that product or alternative product that is judged by FDA to be an adequate substitute. Baxter's written request to FDA shall be signed by senior Baxter officers, including at least one corporate medical officer, and include, at least, the following information in its request: (a) the name of pump(s) and model number(s); (b) data identifying Baxter's market share and the market share for all alternative products used for the potentially medically necessary use; (c) the number of pumps in distribution and available in the market chain; (d) the name and contact information of appropriate medical personnel reporting device shortages in their facility; (e) supporting facts and documentation for Baxter's claim that there is a bona fide shortage, the cause and duration of the reported shortage, and

that the shortage product is medically necessary; (f) data identifying all other available sources of alternative products that can be substituted for the Baxter device; (g) the medical risks posed by the device shortage; and (h) whether the Baxter device has been cleared for marketing by FDA, and for all such products that have manifested failures and/or defects, the supporting data documenting Baxter's corrective action(s) to remedy such failures and/or defects.

F. Any Infusion Pumps or components thereof manufactured, imported, or distributed *solely* for the purpose of complying with the requirements of paragraph 14 (the corrective action plan provision as set forth in paragraph 14), provided that such Infusion Pumps comply with the requirements set forth in Baxter's corrective action plan after its approval by FDA under paragraph 14.

G. Any component for the Colleague and Syndeo Infusion Pumps whose manufacture, processing, packaging, sale, or distribution has been requested by Baxter in writing to FDA pursuant to this subparagraph and authorized by FDA in writing.

12. Upon entry of this decree, Defendants and each and all of their officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including franchisees, subsidiaries, affiliates, and "doing business as" entities), who have received actual notice of this decree by personal service or otherwise, for so long as such persons are in positions of responsibility with Defendant Baxter or any of Defendant Baxter's franchisees, subsidiaries, affiliates, and/or "doing business as" entities, are permanently enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly: (a) causing the introduction or delivery for introduction into interstate commerce, of any infusion pump device that is adulterated within the meaning of 21 U.S.C. §§ 351(c) and 351(h), or misbranded

within the meaning of 21 U.S.C. § 352(t)(2); and (b) causing infusion pump devices that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. §§ 351(c) and 351(h), or misbranded within the meaning of 21 U.S.C. § 352(t)(2).

13. After Defendants receive written communication from FDA pursuant to paragraph 10(F), Defendants shall retain an independent person or persons (the "Auditor") to conduct audit inspections of the operations at Baxter's Infusion Pump Facilities located in the United States not less than once every six (6) months for a period of one (1) year and not less than once every twelve (12) months for a period of three (3) years thereafter, for a total of four (4) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to any of Baxter's officers or employees or their immediate families and may, if Baxter chooses, be the same person or persons described as the Expert in paragraph 10(B).

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") expressing in detail an opinion whether Defendants are in, or are not in, compliance with 21 U.S.C. § 351(h), 21 C.F.R. Part 820, 21 U.S.C. § 352(t)(2), and this decree, and identifying in detail any deviations from 21 U.S.C. § 351(h), 21 C.F.R. Part 820, 21 U.S.C. § 352(t)(2), and this decree ("Audit Report Observations"). As part of every Audit Report, except the first Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations, and report in writing the actions to correct each item enumerated in the prior Audit Report(s), and which items have not been corrected, if any. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier

service or overnight delivery service, no later than twenty-five (25) calendar days after the date the audit inspections are completed. If any Audit Reports identify deviations from 21 U.S.C. § 351(h), 21 C.F.R. Part 820, 21 U.S.C. § 352(t)(2), and/or this decree, FDA may, in its discretion, require that the auditing cycle be extended for a length of time not to exceed four (4) years. In addition, Defendants shall maintain the complete Audit Reports and all of their underlying data in separate files at their facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty-five (35) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of an adverse Audit Report Observation will take longer than thirty-five (35) calendar days, Defendants shall, within fifteen (15) calendar days of receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification describing why the additional time is necessary. That Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved Correction Schedule. Within thirty-five (35) calendar days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observations. Within ten (10) calendar days of the beginning of that review, the Auditor shall report in writing to FDA whether each of the adverse observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

C. The audit inspections and Audit Reports required by this paragraph shall encompass, but not be limited to, the following:

i. Steps taken by Defendants to identify the root causes, or if not precisely known, the most probable root causes, for the failures with the Infusion Pumps, and an evaluation whether Defendants have implemented appropriate steps to correct and prevent such failures.

ii. Defendants' procedures for properly and timely reporting adverse events under 21 C.F.R. Part 803;

iii. Steps taken by management with executive responsibility to ensure continuous implementation of an adequate and effective quality system, including specific written procedures governing management review and quality audits;

iv. Personnel training to perform product failure and corrective and preventive action assessment activities; and

v. Procedures for the CAPA system, including, but not limited to: implementing and verifying or validating corrective actions in accordance with 21 C.F.R. §§ 820.75, 820.1(a)(3), and 820.30(f)-(g); establishing appropriate time frames; conducting and documenting adequate failure investigations; and implementing an effective complaint handling system.

14. Within twenty (20) calendar days after entry of this decree, Defendants shall submit to FDA in writing a detailed Corrective Action Plan to bring the Infusion Pumps currently in use in the United States by physicians, hospitals, pharmacies, and other users/facilities into compliance with the Act, its implementing regulations, and this decree. The written Corrective Action Plan shall

include, among other things: (a) a description and the supporting documentation for each upgrade, modification, and/or action to be taken for the Infusion Pumps previously distributed; (b) the testing conducted to verify and validate the upgrades and/or modifications in accordance with 21 C.F.R. §§ 820.75, 820.1(a)(3), and 820.30(f)-(g); (c) the projected date on which Defendants will implement and complete the Corrective Action Plan; (d) the manner in which the upgrades and modifications will be made to the Infusion Pumps; (e) whether Infusion Pumps will be recalled to implement corrective actions; (f) identification of the root causes, or if not precisely known, the most probable root causes, of the failures with the Infusion Pumps; and (g) a clear statement whether Defendants' believe the proposed upgrades and modifications to the Infusion Pumps proposed in the Corrective Action Plan require premarket clearance from FDA, the reasons for that belief, and whether premarket clearance has been sought and obtained by Defendants. Defendants shall not initiate the Corrective Action Plan until FDA has first provided Defendants with written authorization to do so.

FDA shall respond in writing within forty-five (45) calendar days of FDA's receipt of Baxter's Corrective Action Plan and notify Baxter in writing whether the proposed plan is acceptable. If FDA finds the plan unacceptable, it shall state the basis for finding the proposed plan unacceptable in writing, and Defendants shall submit a revised Corrective Action Plan in writing within twenty (20) calendar days of receipt of FDA's response. FDA's decision regarding the adequacy of Defendants' Corrective Action Plan shall be final.

Defendants shall commence the implementation of the Corrective Action Plan within thirty (30) calendar days of receiving FDA's written authorization. Defendants shall, beginning one month after the date on which implementation of the Corrective Action Plan has begun, and continuing

until its completion, submit to FDA monthly written progress reports updating the status of the Corrective Action Plan. Defendants shall use their best efforts to locate all Infusion Pumps in use by health care professionals in the United States and to obtain the cooperation of such users to implement the corrective actions required by this paragraph. If Defendants have not obtained FDA authorization for the Corrective Action Plan within twelve (12) months after the date this decree is entered, then FDA may take any action(s) it deems appropriate under paragraph 15 of this decree.

15. If, at any time after this decree has been entered, FDA determines, based on the results of an inspection, sample analysis, a report or data prepared or submitted by Defendants, the Expert, or the Auditor pursuant to this decree, or any other information, that Defendants have failed to comply with any provision of this decree, or have violated the Act or its regulations, or that additional corrective actions are necessary to achieve compliance with this decree or the Act, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions with respect to the Infusion Pumps or components thereof located in or to be distributed into the United States, including but not limited to, the following:

A. With respect to Infusion Pump Facilities located in the United States, cease the manufacture, processing, packing, repacking, labeling, holding, and interstate distribution of any or all the Infusion Pumps or components thereof;

B. Cease importing, directly or indirectly, any or all of the Infusion Pumps or components thereof;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to the decree;

D. Submit additional reports or information to FDA;

E. Recall, at Defendants' sole expense, specified adulterated or misbranded Infusion Pumps manufactured, distributed, or sold by Defendants or that are under the custody and control of Defendants' agents, distributors, customers, or consumers;

F. Issue a safety alert; and/or

G. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with the Act, its implementing regulations, and this decree.

16. A. Any order issued by FDA pursuant to paragraph 15 shall be issued by the appropriate FDA District Director, and shall specify the failures giving rise to the order. Unless a different time frame is specified by FDA in its order, within fifteen (15) calendar days after receiving an order pursuant to paragraph 15, Defendants shall notify FDA in writing either that (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific action taken or to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, within fifteen (15) calendar days after receiving Defendants' response, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as the Agency deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decisions in writing. The written notice of affirmance shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and, if they so choose, bring the matter before this court on an expedited basis. Defendants shall continue to diligently implement FDA's order unless the court reverses or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 26.

17. Any cessation of operations or other action described in paragraphs 15-16 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this decree, the Act, and its implementing regulations. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraphs 15-16 shall be borne by Defendant Baxter at the rates specified in paragraph 20.

18. Defendants represent that they do not currently manufacture or distribute any other infusion pumps that have any of the following components and device specifications in common with the Colleague and Syndeo Infusion Pumps: software systems, computer motherboards, processors, sensors, timing circuitry, power systems, and pumping mechanisms. If Defendant Baxter intends to manufacture or distribute an infusion pump(s) with any of the above-listed components in common with the Colleague and Syndeo Infusion Pumps, it shall notify FDA ninety (90) days prior to distribution of the device and describe in detail the use of the same components.

19. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Baxter's Infusion Pump Facilities, and take any other measures necessary to monitor and to ensure continuing compliance with the terms of this decree.

During such inspections, FDA representatives shall be permitted: access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendants' materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any and all devices. FDA will provide Defendants with a receipt for any samples taken pursuant to 21 U.S.C. § 374 and upon Defendants request and at Defendants' own expense, with copies of any photographs or video recordings made. The inspections shall be permitted upon presenting a copy of this decree and appropriate credentials. The inspection authority granted by this decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

20. Defendant Baxter shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this decree. The costs of such inspections shall be borne by Defendant Baxter at the prevailing rates in effect at the time the costs are incurred. As of the date that this decree is signed by the parties, these rates are: $76.10 per hour and fraction thereof per representative for inspection work; $91.18 per hour or fraction thereof per representative for analytical or review work; $0.445 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. FDA shall submit a reasonably detailed bill of costs to Baxter at the address specified in paragraph 23. In the event that the standard rates applicable to

FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the court.

21. Within ten (10) calendar days after the entry of this decree, Defendants shall provide a copy of this decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of its directors, officers, agents, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, franchisees, affiliates, partnerships, and "doing business as" entities) with responsibilities for the manufacture and quality of the Infusion Pumps (hereafter, collectively referred to as "Associated Persons"). In the event that Defendant Baxter becomes associated, at any time after the entry of this decree, with new Associated Persons, Defendants shall (a) within fifteen (15) calendar days of such association, provide a copy of this decree to such person(s) by personal service or certified mail (restricted delivery, return receipt requested) and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the decree was provided. Within twenty (20) calendar days after entry of this decree, Defendants shall provide a copy of this decree to all of Defendants' employees involved in the manufacture, processing, packing, storage, or distribution of the Infusion Pumps, by posting a copy of this decree on Baxter's intranet Web site in such a manner to ensure that it will be viewed by such employees, and shall prominently post a copy of this decree in the employee common areas at all facilities where such employees are located. Baxter shall ensure that the decree remains posted on Baxter's intranet and in the employee common areas for no less than twelve (12) months. Within thirty-five (35) calendar days of the date of entry of this decree, Defendant Baxter shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this paragraph and

identifying the names and positions of all persons who initially received a copy of this decree and the manner of notification.

22. Defendants shall notify the District Director, FDA Chicago District Office, in writing at least fifteen (15) calendar days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the corporate structure of the companies or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this decree. Defendants shall provide a copy of this decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

23. All notifications, correspondence, and communications required to be sent to FDA by the terms of this decree shall be addressed to the District Director, FDA Chicago District Office, 550 West Jackson Boulevard, Chicago, Illinois 60661. All notifications, correspondence, and communications required to be sent to Defendants by the terms of this decree shall be addressed to the Director of the Consent Decree Compliance Task Force at One Baxter Parkway, Deerfield, IL 60015.

24. If Defendants fail to comply with any of the provisions of this decree, including any time frame imposed by this decree, then, on motion of the United States in this proceeding, Defendant Baxter shall pay to the United States of America fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues and an additional sum of fifteen thousand

dollars ($15,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this decree. The amount of liquidated damages in this paragraph shall not exceed ten million dollars ($10,000,000) in any one calendar year.

25. Should the United States bring, and prevail in, a contempt action to enforce the terms of this decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

26. All decisions conferred upon FDA in this decree shall be vested in the sole discretion of FDA, which discretion shall be reviewed, if contested, under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A) and shall be based exclusively upon the written record that was before FDA at the time of the decision. No discovery may be had by either party.

27. If Defendants petition the court for relief from this decree and, at the time of the petition, in FDA's judgment, Defendants have maintained at Baxter's Infusion Pump Facilities a state of continuous compliance with applicable laws and regulations, and this decree for the sixty (60) months preceding the petition and following entry of this decree, Plaintiff will not oppose such petition.

28. This court retains jurisdiction of this action for the purpose of enforcing or modifying this decree and for the purpose of granting such additional relief as may be necessary or appropriate.

E N T E R:

_____
UNITED STATES DISTRICT JUDGE

Date: _____

We hereby consent to the entry of the foregoing:

Respectfully submitted,

By Defendants:

_____

ROBERT L. PARKINSON, JR.
individually and on behalf of
Baxter Healthcare Corporation as its
Chairman and Chief Executive Officer

_____

PETER J. ARDUINI
individually and on behalf of Baxter Healthcare Corporation as its Corporate Vice President and President of Medication Delivery Services

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